

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>CRYSTAL GROSS, et al.</b>	<b>CIVIL ACTION</b>
<b>v.</b>	<b>NO. 19-4385</b>
<b>COLOPLAST CORP., et al.</b>	

Baylson, J.

January 17, 2020

**MEMORANDUM**

**I. Introduction and Factual History**

Plaintiffs sue Coloplast Corp. for the alleged manufacture and sale of a defective pelvic mesh product which was implanted in Plaintiff Crystal Gross in May of 2018. ECF 1, Compl. ¶¶ 11–12, 73.<sup>1</sup> (Crystal Gross’s husband, Timothy Gross, is also a plaintiff. Id. ¶ 2.) Crystal Gross has suffered pain and injury from the mesh’s defects, and she has had to undergo multiple surgeries (and expects to undergo more) to have the mesh removed. Id. ¶¶ 73–85. Some of her injuries are permanent. Id. ¶¶ 84–85. She and her husband claim that the Defendant failed to adequately disclose the mesh’s defects to medical professionals and consumers. Id. ¶¶ 61–66. The mesh in question was originally approved through the FDA’s § 510(k), or “substantial equivalence,” approval process in 2012. Id. ¶ 50. In April 2019, the FDA ordered Coloplast to “stop selling and distributing” this and other products immediately because Coloplast “ha[d] not demonstrated reasonable assurance of safety and effectiveness.” Id. ¶ 71.

The Grosses’ complaint contains eight counts:

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<sup>1</sup> For purposes of this motion, the Court accepts as true the facts contained in Plaintiff’s Complaint. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

- Count I. Strict Liability – Design Defect
- Count II. Strict Liability – Manufacturing Defect
- Count III. Strict Liability – Failure to Warn
- Count IV. Negligence
- Count V. Fraudulent Concealment
- Count VI. Negligent Misrepresentation
- Count VII. Violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”)
- Count VIII. Loss of Consortium

Defendant now seeks to have Counts I-III and V dismissed as legally insufficient and Counts VI-VII dismissed as inadequately pleaded. (ECF 3.) Specifically, Defendant argues that Counts I-III must fail because Pennsylvania law does not permit strict liability claims against manufacturers of medical devices; that Count V must fail because they did not violate any duty to disclose; and that Plaintiffs have not met the more exacting pleading standards that Federal Rule of Civil Procedure 9(b) requires for claims that sound in fraud.

For the reasons that follow, Defendant’s Motion to Dismiss will be DENIED as to Counts I-III and GRANTED, without prejudice and with leave to amend, as to Counts V-VII.

## **II. Procedural History**

Plaintiffs filed suit against Coloplast Corporation and Coloplast Manufacturing US, LLC in this Court on September 20, 2019. ECF 1. Defendant Coloplast Corporation filed a motion to dismiss on November 26. ECF 3. Plaintiffs responded on December 10, ECF 4, and Coloplast Corporation replied on December 17. ECF 5. On December 19, the parties stipulated to the

dismissal of Plaintiffs' claims against Coloplast Manufacturing. ECF 6. Coloplast Corporation remains as the sole defendant in this case.

### **III. Legal Standard**

#### **a. Rule 12(b)(6): Failure to State a Claim**

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” Ashcroft, 556 U.S. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The Court in Iqbal explained that, although a court must accept as true all of the factual allegations contained in a complaint, that requirement does not apply to legal conclusions; therefore, pleadings must include factual allegations to support the legal claims asserted. Iqbal, 556 U.S. at 678, 684. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. at 678 (citing Twombly, 550 U.S. at 555); see also Phillips v. Cty. of Allegheny, 515 F.3d 224, 232 (3d Cir. 2008) (quoting Twombly, 550 U.S. at 556 n.3) (“We caution that without some factual allegation in the complaint, a claimant cannot satisfy the requirement that he or she provide not only ‘fair notice,’ but also the ‘grounds’ on which the claim rests.”). Accordingly, to survive a motion to dismiss, a plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556).

#### **a. Rule 9(b): Allegations of Fraud**

All allegations of fraud must meet the heightened pleading standard of Federal Rule of Civil Procedure Rule 9(b) (the “particularity” requirement). Rule 9(b)’s heightened pleading standard not only gives defendants notice of the claims against them, but also provides increased

measure for protection of their reputation and reduces the number of frivolous lawsuits brought solely to extract settlements. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997).

Rule 9(b) may be satisfied by describing “the circumstances of the alleged fraud with precise allegations of date, time, or place, or by using some means of injecting precision and some measure of substantiation into [the] allegations of fraud.” Bd. of Trs. of Teamsters Local 863 Pension Fund v. Foodtown, Inc., 296 F.3d 164, 172 n. 10 (3d Cir. 2002) (internal quotation marks and citation omitted). Stated another way, the plaintiff must plead the who, what, when, where, and how of the fraud. Institutional Inv’rs Grp. v. Avava, Inc., 564 F.3d 242, 253 (3d Cir. 2009); see Bonavitacola Elec. Constr. v. Boro Developers, Inc., No. 01-5508, 2003 WL 329145, at \*6 (E.D. Pa. Feb. 12, 2003) (Baylson, J.).

However, “courts should be sensitive to the fact that application of [Rule 9(b)] prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud. Accordingly, the normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant's knowledge or control.” In re Burlington, 114 F.3d at 1418 (internal quotation marks and citations omitted). Thus, plaintiffs may plead certain factual allegations based “upon information and belief” but must allege that the necessary information lies within the defendant's control, and their allegations must be accompanied by a statement of the facts upon which the allegations are based. Craftmatic Sec. Litig. v. Kraftsow, 890 F.2d 628, 645 (3d Cir. 1989). Boilerplate and conclusory allegations will not suffice. In re Burlington, 114 F.3d at 1418.

b. Open Questions of Pennsylvania Law

“In diversity cases, ‘where the applicable rule of decision is the state law, it is the duty of the federal court to ascertain and apply that law, even though it has not been expounded by the highest court of the state.’” Jewelcor, Inc. v. Karfunkel, 517 F.3d 672, 676 n.4 (3d Cir. 2008) (quoting Pennsylvania v. Brown, 474 F.2d 771, 777 (3d Cir. 1967)). In so doing, this Court must “consider relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.” Packard v. Provident Nat’l Bank, 994 F.2d 1039 (3d Cir. 1993) (quoting McKenna v. Ortho Pharm. Corp., 622 F.2d 657, 663 (3d Cir. 1980)).

“Although not dispositive, decisions of state intermediate appellate courts should be accorded significant weight in the absence of an indication that the highest state court would rule otherwise.” Jewelcor Inc., 517 F.3d at 676 n.4 (quoting City of Philadelphia v. Lead Indus. Ass’n, Inc., 884 F.2d 112, 123 (3d Cir. 1993)). Although such decisions are not binding, nor are they “to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise.” Id. (quoting N. Ins. Co. of N.Y. v. Aardvark Assocs., Inc., 942 F.2d 189, 193 (3d Cir. 1991)).

**IV. Discussion**

a. Counts I-III: Strict Liability

Pennsylvania law, applying Section 402A of the Restatement (Second) of Torts, presumes that products can be the subject of strict products liability suits. Tincher v. Omega Flex, Inc., 104 A.3d 328, 382, 389 (Pa. 2014) (citing Restatement (Second) of Torts § 402A cmt. b). The issue here is whether the Pennsylvania Supreme Court would extend a certain exemption from this

presumption to medical devices. Comment k to Section 402A exempts certain “unavoidably unsafe products” from the presumption of strict liability. In 1996, in Hahn v. Richter, the Pennsylvania Supreme Court adopted comment k to bar strict liability claims involving prescription drugs. See Hahn v. Richter, 673 A.2d 888, 890 (1996). Prescription drugs are thus indisputably exempt from strict liability under Pennsylvania law. Id.; see also Tincher v. Omega Flex, Inc., 104 A.3d 328, 382 (Pa. 2014) (citing Hahn, 673 A.2d at 888).

Defendant asks the Court to conclude that the Pennsylvania Supreme Court would extend Hahn to prescription medical devices as the pelvic mesh at issue here. Its argument relies mainly on the 2006 case of Creazzo v. Medtronic, Inc., in which the Superior Court, on appeal from a grant of summary judgment, extended the immunity flowing from Hahn and comment k to medical devices, because it could “find no reason why the same rationale [sic] applicable to prescription drugs may not be applied to medical devices.” 903 A.2d 24, 27, 32 (Pa. Super. 2006). The *pro se* plaintiffs in Creazzo do not appear to have litigated the point thoroughly,<sup>2</sup> and the Creazzo court discussed the issue only briefly. See id. at 26, 32.

Following Creazzo, a few Pennsylvania Supreme Court decisions cautioned, both in general terms and with specific reference to Hahn- and comment k, against lightly altering the common law of products liability.<sup>3</sup> These decisions, “indications that the highest state court would

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<sup>2</sup> “They cite no authority . . . nor do they provide significant analysis of the language they seek to apply.” Id. at 32.

<sup>3</sup> Following these decisions, federal district courts applying Pennsylvania law, faced with the same triad of strict liability claims as in this case, have reached varying conclusions. Compare, e.g., Schrecengost v. Coloplast Corp., No. 3:17-cv-220, 2019 WL 6465398, at \*12 (W.D. Pa. Dec. 2, 2019) (Gibson, J.) (allowing all three claims to proceed), with Smith v. Howmedica Osteonics Corp., 251 F. Supp. 3d 844, 849 (E.D. Pa. 2017) (Beetlestone, J.) (allowing manufacturing defect

rule otherwise,” Jewelcor Inc., 517 F.3d at 676 n.4, vitiate Creazzo’s reliability as evidence of how that court would decide whether comment k covers medical devices.

First, the Pennsylvania Supreme Court has strongly discouraged Pennsylvania courts from carving out certain categories of products for special treatment within the common law of products liability. Tincher, 104 A.3d at 396 (“Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which . . . categories and types of products, should be exempt.”). That

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claim to proceed), and with Rosenberg v. C.R. Bard, Inc., 387 F. Supp. 3d 572, 576–81 (E.D. Pa. 2019) (Robreno, J.) (allowing no claims to proceed).

The Court makes two observations about how Defendant characterizes the district court cases it cites. The first concerns Defendant’s characterization of those cases. The second concerns Defendant’s characterization of the exhaustiveness of its citations.

First, Defendant asserts twice that “every other [i.e., besides Judge Gibson in Schrecengost] federal court that has addressed the issue,” including post-Tincher cases, would entirely dismiss Plaintiffs’ strict liability claims. See Def. Reply Br. at 1, 7. This is incorrect. Many federal district courts, including in cases that Defendant cites to, have allowed strict-liability manufacturing-defect claims to proceed. See, e.g., Smith v. Howmedica Osteonics Corp., 251 F. Supp. 3d 844, 849 (E.D. Pa. 2017) (Beetlestone, J.) (cited by Defendant); Wallace v. Bos. Sci. Corp., 2018 WL 6981220, at \*7–8 (M.D. Pa. Nov. 29, 2018) (Carlson, M.J.) *adopted*, 2019 WL 137605 (M.D. Pa. Jan. 8, 2019) (Mariani, J.) (cited by Defendant).

Second, on Page 7 of its Reply Brief (ECF 5), Defendant provides a string citation to “*every one* of the nearly 30 other [i.e., besides Schrecengost] federal district courts *to ever address this issue*.” (emphasis added). However, Defendant’s list of “every” other district court case “to ever address this issue” appears to be missing at least four cases. Some of those favor Defendant, and some do not. See Wagner v. Kimberly-Clark Corp., 225 F. Supp. 3d 311 (E.D. Pa. 2016) (Stengel, J.), Wilson v. Synthes USA Prods., LLC, 116 F. Supp. 3d 463 (E.D. Pa. 2015) (Schmehl, J.); Terrell v. Davol, Inc., Civil Action No. 13-5074, 2014 WL 3746532 (E.D. Pa. July 30, 2014) (Slomsky, J.); Bergstresser v. Bristol-Myers Squibb Co., Civil Action No. 3:12-1464, 2013 WL 1760525 (M.D. Pa. Apr. 24, 2013).

The Court assumes these errors are unintentional.

discouragement is strongest where the record is lacking. See id.; see also Lance v. Wyeth, 85 A.3d 434, 454 (Pa. 2014) (citing Seebold v. Prison Health Servs., 57 A.3d 1232 (Pa. 2012)) (stating that Pennsylvania courts should not use the adjudicatory process to expand or contract the common law of products liability without “a comprehensive discussion of the competing policies and . . . the sort of record (including empirical information) which would support an informed, legislative-type judgment . . .”).

Second, the Pennsylvania Supreme Court has more specifically cautioned Pennsylvania courts against thoughtlessly extending Hahn and comment k. In 2014, the Pennsylvania Supreme Court said of Hahn that it “applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k . . . . [T]he truncated analysis in the Hahn line offers a poor foundation for extrapolation.” Lance, 85 A.3d at 452 n.21. And as far as comment k is concerned, the Pennsylvania Supreme Court has sympathetically acknowledged scholarship calling it (among other things) “an enigma,” “a masterpiece of confusion and double-speak,” and a “monumental failure.” Id. at 451 (quoting Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 Geo. Wash. L. Rev. 76, 81–82 (1994); and James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs Are Different*, 111 Yale L.J. 151, 180 (2001)).

This post-Creazzo methodological guidance undermines Creazzo’s reliability as evidence of what the Pennsylvania Supreme Court would decide. Creazzo, in a few sentences, apparently with limited briefing, categorically extended comment k and Hahn’s reasoning to medical devices. But Tincher and Lance discourage Pennsylvania courts from making such categorical decisions at all, especially briefly, especially on limited records, and especially based on comment k and Hahn.



Creazzo, therefore, is not persuasive authority of how the Pennsylvania Supreme Court would decide this question. This Court, therefore, cannot dismiss these claims based on Creazzo.

The Pennsylvania Supreme Court, encountering these same claims in the same procedural posture, may allow them to proceed. The Pennsylvania Supreme Court has cautioned Pennsylvania courts against making categorical carveouts from the presumption of strict liability without, at the least, a rich factual record on the policy issues that should inform a common-law analysis of whether to allow these claims. Because this Court faces the question of whether to allow these claims to proceed on a Rule 12 motion to dismiss, this Court has no such factual record. This Court concludes, considering all the circumstances, including the distinct possibility the Pennsylvania Supreme Court may allow these claims to proceed, a better result is to allow Plaintiffs' claims to proceed in this case, at this stage. Defendant is not prejudiced because there are many similar claims proceeding across the United States.

The Court will therefore DENY Defendant's Motion to Dismiss as to Counts I-III.

b. Counts V-VII: Fraudulent Concealment, Negligent Misrepresentation, and Violations of the Pennsylvania UTPCPL

The Court will dismiss Counts V,<sup>4</sup> VI, and VII as inadequately pleaded, without prejudice.

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<sup>4</sup> Anticipating another motion to dismiss should Plaintiffs file an amended complaint, the Court will comment briefly on three of Defendant's legal arguments concerning Count V.

First, Defendant argued that the fraudulent-concealment claim is barred because it is essentially a restyled failure-to-warn claim, and, per Hahn, the only remedy for a failure to warn is negligence. ECF 3-1, Def. MtD Br. at 7. However, as the briefing stands, the Court does not consider it any more appropriate to apply Hahn to bar this claim at this stage than it saw to apply Hahn to bar Plaintiffs' strict liability claims at this stage.

Second, Defendant argues that Plaintiffs must show that information was withheld not from them, but from Crystal Gross's healthcare provider. Id. at 7-8. Defendant's main citation for this

Because Plaintiffs’ fraudulent concealment, negligent misrepresentation, and UTPCPL claims allege fraudulent conduct, Plaintiff must meet the pleading requirements of Rule 9(b). See Travelers Indem. Co. v. Cephalon, Inc., 620 Fed. App’x 82, 85 n.3 (3d Cir. 2015) (negligent misrepresentation); Webb v. Volvo Cars of N.A., LLC, Civil Action No. 13-2394, 2018 WL 1470470 (E.D. Pa. Mar. 26, 2018) (Baylson, J.) (citing Travelers, 620 Fed. App’x at 85 n.3; and Petruska v. Gannon Univ., 462 F.3d 294, 310 (3d Cir. 2006)) (negligent misrepresentation and UTPCPL); Marcum v. Columbia Gas Transmission, LLC, Civil Action No. 19-3873, 2019 WL 6217878, at \*2 (E.D. Pa. Nov. 20, 2019) (Beetlestone, J.) (fraudulent concealment).

However, facts are missing, and the allegations are completely conclusionary. Assuming Plaintiff herself does not have specific knowledge of the facts, that does not excuse her counsel from doing sufficient investigation and research to ascertain facts in the “information market place” concerning these claims, and to include those facts in these common law counts. The

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proposition is to a concurrence in a non-precedential Pennsylvania Superior Court opinion. See id. (citing Thomas v. Smith Kline Beecham Corp., No. 2461 EDA 2012, 2013 WL 11250727, at \*8 (Pa. Sup. Ct. Nov. 27, 2013) (Strassburger, J., concurring))).

Third, Defendant argues that Pennsylvania law does not impose a duty on Defendant to disclose any more information than it did. ECF 5, Def. Reply Br., at 9–10. However, as one of the cases Defendant has cited, id. at 9, acknowledges,

[a] duty to speak may also arise . . . as a result of one party’s reliance on the other’s representations, if one party is the only source of information to the other party, or the problems are not discoverable by other reasonable means. A duty to speak may also occur when disclosure is necessary to prevent an ambiguous or partial statement from being misleading[ or] where subsequently acquired knowledge makes a previous representation false . . . .

City of Rome v. Glanton, 958 F. Supp. 1026, 1038–39 (E.D. Pa. 1997) (Katz, J.); see also Restatement (Second) of Torts § 551. These duties could potentially apply in this case.

burden is not unreasonable because there are many cases making the same claims, they have been reported frequently in newspapers, in legal journals, and there are also cases in which documents have been made public and depositions can be searched for facts to support these claims. Merely because these allegations are routinely copied from one Complaint to the other does not excuse following Rule 9(b) for these types of claims. With particular regard to the Pennsylvania Unfair Trade Practices claim, this judge has consistently required plaintiffs to state specific facts that, if proved, would constitute violation of this statute.

The Court will therefore GRANT Defendant's Motion to Dismiss as to Counts V-VII, without prejudice and with leave to amend to add additional facts supporting these claims.

**V. Conclusion**

For the foregoing reasons, Defendants' Rule 12 Motion will be denied as to Counts I-III and granted as to Counts V-VII, without prejudice and with leave to amend. An appropriate order follows.

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